ADMINISTERING FOLLOW-UP LONGITUDINAL MONITORING SURVEYS

1. PURPOSE
This document describes the process by which DeWorm3 study staff will administer follow-up longitudinal monitoring surveys to eligible participants. Data collected at interim time points in the longitudinal cohorts will serve to assess rates of change in STH prevalence, quantify reinfection and for model validation.

2. INTENDED USERS
All DeWorm3 staff; including field managers, field supervisors and field officers, who will be planning, overseeing and/or administering the longitudinal follow-up surveys in all intervention and control clusters.

3. RESPONSIBILITIES
All DeWorm3 study staff should understand and follow this SOP prior to conducting follow-up longitudinal monitoring surveys. It is the responsibility of the site’s Principal Investigator (PI) to ensure that all study staff comply with this SOP during the administration of longitudinal monitoring surveys.

4. DEFINITIONS
4.1. Longitudinal study: An observational research method in which data is gathered on the same subjects repeatedly over a period of time. Longitudinal research projects can extend over years or even decades.

4.2. Longitudinal Monitoring Cohort (LMC) is a follow-up study of an age-stratified cohort of residents in each cluster of the DeWorm3 study, identified at baseline and followed until the endline of the study. Its purpose is to track STH prevalence and reinfection patterns over time.

4.3. Longitudinal monitoring survey participant list: A list of individuals from each cluster who are enrolled in the Longitudinal Monitoring Cohort.


4.5. Sampling group 1: Children aged ≥ 1 years to 5 years (from 1st to 5th birthday)

4.6. Sampling group 2: Children aged ≥ 5 years to 15 years (from 5th to 15th birthdays)

4.7. Sampling group 3: Adults aged ≥ 15 years and older (from 15th birthday)

4.8. Exclusion criteria are conditions which prevent participation in the Longitudinal Monitoring Cohort. Exclusion criteria include: individuals who cannot be confirmed as living in the study clusters or who plan to move out of the study area within the study period; adults who do not provide informed consent, or children 7 years and above who refuse assent and children less than 12 months at the time of the baseline survey.

5. REQUIRED MATERIALS
5.1. Smartphone preloaded with SurveyCTO Household Questionnaire and Sampling Form
5.2. Longitudinal monitoring survey participant sample list
5.3. Study Information Sheets, in local language
5.4. Longitudinal monitoring survey consent form in local language
5.5. Longitudinal monitoring survey assent form in local language
5.6. Clipboard and black pen
5.7. Ink pad, and wiping cloth
5.8. Binder or folder for filing all completed Consent Forms
5.9. One barcode per individual
5.10 Coloured dot stickers / various colour permanent marker pens
5.11 Stool collection instructions
5.12 Stool Collection Kits (newspaper, tissue roll, stool container, wooden sticks, bag)
5.13 Permanent ink marker
5.14 Latex gloves

6. PROCEDURE
6.1. Survey preparation

a) Follow-up longitudinal monitoring surveys will be conducted at 12-month intervals following the baseline survey. All individuals who were enrolled into the Longitudinal Monitoring Cohort during the baseline survey will be included on the Longitudinal Monitoring Survey Participant List. This includes those who did not provide a stool sample at baseline.

b) In advance of the longitudinal monitoring survey, the site coordination team should conduct a sensitization visit or phone call to village leaders to ensure that they are aware of the survey in advance of the survey team’s visit.

   i. During the sensitization meeting/call, the survey coordinator should state the purpose of the survey and discuss an optimal day or time for the survey team to start the visits in order to maximize participation.

c) Prior to conducting the longitudinal survey, the trial coordinator should ensure that the teams have the Longitudinal Monitoring Survey Participant List.

d) If required, the field supervisors should arrange for a village escort to be available to walk with the field officers during the survey and take them to the households to reintroduce them.

e) Stool-collection kits should be prepared in advance so that these can be ready to pick up and taken to the field in the morning (approximately 12 kits per field officer per day). To prepare the kits:

   i. Cut the newspaper into pieces of approximately 7x7cm.
   ii. Tear off the tissue roll, counting several squares per kit.
   iii. Include a wooden spatula/stick.
   iv. Include a stool container
   v. Compile each kit in a small opaque bag.

f) The barcode stickers should be printed, two will be printed for each individual on the Longitudinal Monitoring Survey Participant Sample List with the 9-digit participant’s ID. One to be placed on the lid of the stool container and the second to act as a replacement sticker if needed. Each field officer should take the barcode stickers for the specific individuals they will be visiting that day.

g) Field officers should ensure they have the latest version of the SurveyCTO Household Questionnaire and Sampling Form on their smartphone, and that the smartphone is fully charged.

6.2. Locating and approaching the household

a. For each sampled participant the Longitudinal Monitoring Survey Participant List provides information collected at the census (Admin levels including village, Household ID, Household Head Name, Household Address/Information, Household Phone Number, Sampled Individual Name(s), Sampled Individual age, Sampled Individual sex, Sampled Individual ID).
b. Open the SurveyCTO Follow-up Longitudinal Monitoring Survey Form. Proceed through the form selecting the block you are in (India only), followed by the correct field officer name. When it asks you to "select the type of visit" there are two options: Consent and questionnaire OR Sample collection only. Select [Consent and questionnaire].

c. Use the information on the Longitudinal Monitoring Survey Participant List to select the household and individual that you are visiting. Enter the correct administration levels (for example, PHC, HSC, Village) for the household you are visiting (take this information for the household from the Longitudinal Monitoring Survey Participant Sample List) and finally select the individual. The household ID will be displayed alongside the sampled individual and head of household’s names name. Double check this against the Longitudinal Monitoring Survey Participant List.

d. The smartphone will display further information for the household, such as address or locator information and telephone number of the household. Use this to locate the household. Call the household phone number for directions if you cannot locate the household. Then select [Yes].

e. You can use the next screen that displays a note with the household head and information to locate the household in Google maps.

i. If you have data available, click on the displayed link at the bottom of the note, and the phone will switch to Google Maps and display directions to the household’s coordinates. Once you have arrived at the household, you can switch back to SurveyCTO and swipe to the next screen. The form will ask you if you have internet access to allow the link to the map to work. Select [yes] in this case, as you were able to use the link directly.

ii. If you do not have data available, it’s possible to copy the coordinates into Google Maps manually and obtain directions. Swipe past the note with the link, and the form will ask you if you have internet access to allow the link to the map to work. If you select [no] then the form will present the option of searching for the household using the GPRS functionality of the phone (which does not require internet access).

iii. If you do not need to use the Google Maps navigation to locate the household, then you can swipe to the next question.

f. The following screen will say “Were you able to locate the household?” If you were, select [Yes].

g. If it is not possible to locate the household using the information, select [No] for were you able to locate the household. Save and finalise the form and report this to the field supervisor.

h. If, when you arrive at the house, the entire household has moved away from the area, select [No] for were you able to locate the household.

i. If the participant is a PSAC or SAC the screen will show “Try to speak with [hoh_name] who was the first listed person in the household (provided consent)”. If the participant is an adult then the screen will show “Approach the household now and try to speak with [participant_name]”.

j. The form will then ask you to confirm whether the enrolled individual is present at the time of visit.

k. If not present, select [No, participant unavailable]. After this, record how many times
you have visited this person, and then arrange a time to call back. The same option
will be selected if the entire household is not available. You will be told on the next
screen “Nobody is home, you have two more times to contact this person. Make a
note to come back to the household on another occasion. Save and finalise the form
now.”

l. If you select [No, deceased], [No, individual absent for survey period], [No, individual
not eligible] or [No, permanently moved away] the form will end, Save and finalise
the form now.”

m. Ask if the household’s DeWorm3 Study Card is available, and indicate [Yes] on the
phone if it is. Ask to see this and scan the barcode on the Card. If not, select [No]
and indicate why the Card is not available.

n. If the card is not available, select the method of entry for the Household ID you will
use. The preferred option is scanning the Household’s copy of the consent form,
then the extra sticker in the census log you have taken to the field, and the last option
is entering the ID manually from the participant sample list you have taken to the
field.

o. It is possible to save the form and exit at any point (without finalizing). Then you can
go into saved forms and reopen the form to finish it. For example, if the selected
participant is not currently available but nearby and on their way save
the form and
reopen it within an hour or two. If you won’t be able to complete the form before the
end of the day, save, finalise and submit the form.

6.3. Demographics

a. The form will then display the participant’s name, age and sex. Confirm with the
participant or their guardian that the listed age and sex are correct. If both are correct,
select [none] and proceed to the next question.

b. It is possible that a change in the participant’s age will result in them moving into a
different age consent group. In this instance the form will display a flag indicating
what consent procedures should be followed:

1. Moved from age group 1-6 years to age group 7-17 years: Written
assent must be provided by the participant. Follow the steps outlined in
SOP_303. Administering the baseline longitudinal survey section 6.5 and
then proceed to participant questions

2. Moved from age group 7-17 years to age group ≥ 18 years: Informed
consent must be provided by the individual. Follow the steps outlined in
SOP_303. Administering the baseline longitudinal survey section 6.5 and
then proceed to participant questions

c. If updated consent or assent is not provided, then the participant must be dropped
form the longitudinal monitoring cohort. Select this option, thank the individual for
their time and then proceed to save and finalise the form.

d. After completing the consent procedures check with the participant or their guardian
that they agree to answer questions and provide a sample. If they agree to this select
[yes] and proceed to the next question.

e. If they do not agree to answer questions and provide a sample select [no]. After this
check with the participant or their guardian if they agree for someone from the study
team to call back at another time to conduct the survey. Record their response and
then save and finalise the form.

f. If the participant or their guardian agrees to answer questions and provide a sample
indicate whether the section on household water treatment and storage needs to be
completed. This section should only be skipped if it has already been completed for another participant at the same household in this round of the longitudinal monitoring survey.

6.4. Household Questions

a. If you indicate that they are required, household-level questions will then be asked. These should preferably be asked to the household member who answered the questions during the latest census – select the name of the individual who answered the questions last time round.

b. The next question asks if that individual is present and able to speak with you. If they are, conduct the household questions with him/her. However, if that individual is not available, the questions can be answered by the participant who will provide the stool sample or their guardian.

c. The screen displays the answer given to the question on main source of drinking water in the census and you then ask some follow up questions on whether the household does anything to the water to make it safe. If they say yes, it will ask what they do. If they say they purchase bottled water they will be asked how much money each month they spend on bottled water.

d. Ask to observe how drinking water is stored in the household. If permitted, record the method of storage and observe whether stored drinking water is currently available.

e. Ask to see where household members most often wash their hands. Record the type of handwashing facility available. Observe whether water is available, and whether soap, detergent or other cleansing material is available.

f. Once you have finished these questions, click to indicate you have completed the household questionnaire and you will now move to the participant questionnaire.

g. Once this household questionnaire module has been completed and the form is finalized and sent, if you go back in future to sample another participant for the longitudinal survey in this household, these questions will not appear.

6.5. Participant Questions

a. Next a set of questions will be asked to the participant (or the guardian if the participant is under 5 years).

b. Indicate whether the participant has swallowed medicine for worms in the last year. If the answer is yes, also ask where they got the medication.

c. Observe and fill in the type of shoes the participant is wearing at the time the survey is conducted.

d. Ask the participant where they usually go to defecate when at home, then ask whether they used a toilet facility last time they had to defecate at home. If the answer is no, ask why the participant to give you the main reason why they did not use a toilet facility and select an option or specify another reason.

e. Repeat the questions above for when the participant is out and about, for example, at work.

f. Then ask the participant where they were when they last drank water and select the appropriate option.

g. If the participant reported usually using a toilet facility at home, the survey will request to observe the facility. Select [observation possible/permitted] if you can
observe it, and [observation not possible/permitted] if not. These must be observations made by you, not reported by the participant/household.

h. Record the location of the toilet, and how long it takes you and the participant to walk there if not in the dwelling or in their yard/plot.

i. Then observe and record the type of toilet.

   i. **Pit latrine with open pit/only branches** – A latrine without a squatting slab, platform or seat. An open pit is a rudimentary hole in the ground where excreta is collected. It may have bare branches over it to stand on.

   ii. **Pit latrine with slab (cement or concrete)** – A pit latrine where the pit is **fully covered** by a concrete or cement slab fitted with either a squatting hole or seat.

   iii. **Pit latrine with the traditional platform** – A pit latrine where the pit is **fully covered** by a solid platform built of local materials such as logs plastered with mud.

   iv. **Ventilated improved pit latrine (VIP)** – A dry pit latrine ventilated by a pipe extending above the latrine roof. **Floor can be a slab or a traditional platform.** The open end of the vent pipe is covered with gauze mesh or fly-proof netting. If the vent pipe is not covered by a gauze mesh or fly-proof netting, the facility should be classified as a pit latrine with slab or traditional platform not a VIP latrine. The inside of the VIP latrine is kept dark. If the door of the VIP superstructure is missing so that it is no longer dark inside the latrine, the facility should be classified as a pit latrine with slab or traditional platform, not a VIP latrine.

   v. **Water-borne: Flush or pour-flush toilet** – A flush toilet uses a tank (cistern) for flushing water and has a water seal, which is a U-shaped pipe, below the seat or squatting pan that prevents the passage of flies and odors. A pour flush toilet uses a water seal, but unlike a flush toilet, a pour flush toilet uses water poured by hand for flushing (no cistern used).

j. If you select [Water-borne toilet], ask or observe to where the toilet flushes:

   i. **Piped sewer system** - A system of sewer pipes (also called sewerage) that is designed to collect human excreta (feces and urine) and wastewater and remove them from the household environment.

   ii. **Septic tank** - An excreta collection device consisting of a water-tight settling tank normally located underground, away from the house or toilet.

   iii. **Flush to pit latrine** - A system that flushes excreta to a hole in the ground.

   iv. **Flush to somewhere else** - A system in which the excreta is deposited in or nearby the household environment in a location other than a sewer, septic tank, or pit, (for example, excreta may be flushed to the street, yard/plot, drainage ditch or other location.)

   v. **Flush, don’t know**

k. If it is a pit latrine, observe whether there is visible faeces round the edge. You will be able to quickly observe from the doorway of the toilet facility whether the pit opening or toilet/squatting pan have visible faeces or staining around the edge.

l. If it is a pit latrine, use the torch on the phone to look inside and observe whether there is visible faeces in the bottom of the pit.

m. Observe and record the material of the slab/floor of the toilet facility (Enter the predominant material observed), and the type of anal cleansing materials available, if any. Materials can be unused or used and discarded in the toilet facility or pit.
n. Step inside and observe whether the toilet facility has a door that closes and locks from the inside. Then observe the type of walls and roof of the toilet facility. Next record whether there is a well-worn path leading from the house to the toilet facility.

o. Finally observe whether there are facilities for washing hands within 10m of the toilet facility. If these are the same handwashing facilities observed previously (if still in or near the main household, then record [Same as previously observed].

p. The next module of the Longitudinal Monitoring Follow-up Survey Form relates to the stool sample collection.

6.6. Stool sample collection

a. Participants who have answered the questionnaire and have signed the relevant consent form in this round or a previous round of the LMC will be asked to provide a stool sample to be sent to the lab for immediate analysis using Kato-Katz and for storage for subsequent testing via qPCR. Confirm with the participant that they are able to provide a stool sample at this moment.

b. Introduce the Stool Collection Kit materials to the participant (newspaper, tissue roll, stool container, wooden sticks, small opaque bag). Explain the contents of the Stool Collection Kit:
   i. Newspaper will be used to “receive” or “collect” the stool
   ii. The wooden spatula is used to transfer a portion of the stool to the container
   iii. The tissue roll is for wiping themselves
   iv. The container will be used to carry the stool sample back to the laboratory
   v. The bag is to protect their privacy.

c. Apply the appropriate barcode sticker with the word “stool” to the lid of the container before you give the pot to the participant. This barcode must match the participant ID on the Longitudinal Monitoring Survey Participant Sample List.
   i. If the participant cannot deposit the sample now and the container is to be left for a call-back visit later in the day or the following morning, the barcode must be placed on the container prior to giving it to the participant.

d. Do not stick the barcode to the side of the stool container, as this is a curved surface and cannot be scanned. Do not stick it to the base of the pot, as if this is put down on a muddy/wet surface the barcode will be soiled.

e. Write the participant’s name on the side of the stool container in permanent marker.

f. If more than one individual has been sampled for the Longitudinal Monitoring Survey within the household, two pots may have to be left for collection the following day. To prevent the wrong lid (with the barcode) being placed on the wrong stool container, use coloured stickers (or coloured marker pens) to stick on the lid and base of the container, so that the participants know to put the lid with the red dot on the container with the red dot and the lid with the green dot on the container with the green dot.

g. When collecting the stool containers ensure that the coloured dots on the top and bottom of the containers are matching.

h. Give the participant the following instructions:
   i. Ask the participant to go to the place where they usually defecate, preferably a toilet facility. If not, wherever they would usually go.
   ii. Ask them to place the newspaper on the floor of the toilet area or ground, and deposit the stool on the newspaper.
iii. Using the wooden spatula they should collect enough stool to fill 2/3 of the container (you can mark a line on the container to indicate the amount required). Then they put the lid on tightly.

iv. Inform them to use the tissue roll for wiping themselves

v. Once the collection is complete they should dispose of the newspaper, tissue roll and wooden stick in the latrine facility if available.

vi. The collected stool in the container should be placed back into the bag and handed to you.

i. A glove can be worn when receiving the stool from the participant, although there should be no direct contact with the stool as it will be in a container within a bag. Fresh stool is warm and the container may be slightly moist. It is important to try and keep the barcode clean and not soiled with stool.

j. When the participant hands over the stool container, discretely check the sample (without removing the lid). Note down any comments in the SurveyCTO Longitudinal Monitoring Follow-up Survey Form

k. Scan the ID on the stool container into the Form. If the ID is soiled and cannot be scanned, enter the ID manually.

l. If the ID does not match the ID of the participant logged in the survey, this will be flagged and you will not be able to proceed.

m. Once collected from the participant and logged, place the stool container in the cooler box ready to transport to the laboratory. Save and finalise the form.

n. If the participant is ready and able to give the stool sample at that stage, the stool sample should be collected the same day. Participants unable to provide a stool sample will be left with the stool containers and asked to provide a fresh morning stool the next day, following the stool collection directions provided.

o. Arrange a time and location for the collection of the stool containers (ideally around 9-10 am the following morning. The filled stool containers should ideally be kept in the house until pick up. However, an outside location is also acceptable if the containers are above the ground in a shaded and accessible place)

p. If the sample is to be collected the next day, the participant must deposit the stool when they defecate in the morning. It must not be deposited the previous evening because any hookworm eggs will have hatched before the stool reaches the lab and the eggs cannot be seen and counted using Kato-Katz

q. Insist the stool must be fresh, not from another day (for those who do not have toilets and can identify a previously deposited stool). Also emphasize the importance of the stool being collected being from the same individual who was sampled and answered the questions.

6.7. Returning to collect a stool sample later

a. If you have returned to collect a sample at a call-back visit, open a new form. Select the block you are in, followed by the correct field officer name. When it asks you to "select the type of visit" select [Sample collection only].

b. Use the information on the Longitudinal Monitoring Survey Participant List to select the individual you are visiting. Enter the correct administration levels (for example, PHC, HSC, Village).

c. The form will then display the names of all the individuals in that village for whom you have obtained consent, completed the survey, and left a stool container. If you have not yet completed the “Consent and questionnaire” survey form from anyone...
in the village for the Longitudinal Monitoring Cohort, you will not be able to proceed as no names will appear.

d. Select the individual you are collecting the stool pot from in that village. Then once you have selected this, the rest of the household and locator information will appear to help you locate the household and confirm your selection.

e. When you are handed the pot to scan, report anything problematic with the sample, if noticed, otherwise click “No comment”.

f. Then scan the barcode on the top of the container. **Only if it is spoiled**, enter the code manually (A monitoring form will record how many times the barcode is manually entered versus scanned). Enter the related information for the sample.

g. If the sample ID scanned or entered is not the same as the ID of the participant you selected this will be flagged and you will not be able to finalise the form.

h. If the barcode and participant ID match, you will be asked to confirm with the household members that the individual listed actually provided the stool sample. Additionally enter the approximate time that the stool was deposited. Then save and finalise the form.

i. Make arrangements for the samples to be delivered to the lab within 8 hours of being deposited by the participant.

j. In the event that the participant is not present at this return visit, or has been unable to provide a stool sample the following day, another call-back will be planned. Ask the participant or his/her family when the most appropriate time for collection would be. Conduct a minimum of three call back attempts (on three separate days) for stool collection in the longitudinal monitoring survey.

k. Any participant unable to produce a stool sample during the three attempts should be excluded from the cohort.

l. In the event that a participant expressly requests to be removed permanently from the Longitudinal cohort, the supervisors and data manager will document the information and fill a “LMC withdrawal form”. Supervisors will need to personally visit and confirm every case of withdrawal reported to them by enumerators.

m. The refusal to provide a stool sample during the LMC visit DOES NOT constitute a withdrawal case. Withdrawal forms will only be filled when a participant says he or she no longer wishes to be visited as part of the LMC activity.

### 6.8. Survey completion

a. Save and finalise the SurveyCTO form.

b. Prior to leaving the household, tell participants:
   i. That in intervention clusters all individuals will be treated during community-wide MDA, whereas in control clusters, pre-SAC and SAC will be treated in schools.
   ii. In control clusters, all adults with moderate to heavy intensity infections identified using Kato-Katz will be followed-up with for treatment.

c. Ask the participants if they have any further questions and thank them for their participation.
## DeWorm3 SOP | Standard Operating Procedure 305
Title: Administering the baseline longitudinal monitoring survey

### Current Document

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<td>Hugo Legge</td>
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<tr>
<td>Date:</td>
<td>9 November 2018</td>
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<tr>
<td>Reviewed by:</td>
<td>William Oswald</td>
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<tr>
<td>Date:</td>
<td>14 November 2018</td>
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<tr>
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<td>Katherine Halliday</td>
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<td>Date:</td>
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<tr>
<td>Reviewed by:</td>
<td>Elodie Yard</td>
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<td>Reviewed by:</td>
<td>Fabian Schaer</td>
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### Approvals

_I have reviewed and approve this SOP for implementation._

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<tr>
<th>Principal Investigator</th>
<th>Signature</th>
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### Document History

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<td>Hugo Legge, William Oswald, Katherine Halliday</td>
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| 2           | 15 April 2019   | Hugo Legge, Katherine Halliday, Elodie Yard, Fabian Schaer | • Participant withdrawal points (6.7 L-M) added.  
• Reference to amending age and sex removed |
## SITE NAME

**Read and Review Log**
List of individuals who read and reviewed the SOP

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<th>Name</th>
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*By signing this log, study staff confirm that they have read and understood the content of the SOP*